

Sub E2
mixture components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture; and
analyzing the components of each selected reagent mixture.

Remarks

Claims 1 and 31 have been amended, and therefore claims 1, 3-6, 31 and 33-44 are now pending in this application. In view of the above amendments and the following remarks, it is respectfully submitted that these claims are allowable.

Claims 1, 3-6, 40 and 42-44 stand rejected under the judicially-created doctrine of obviousness-type double patenting in view of Applicant's prior U.S. Patent No. 5,840,254. Accordingly, Applicant submits herewith a terminal disclaimer in full compliance with 37 CFR 3.73(b). Payment in the amount of \$55.00 is enclosed herewith to cover the statutory disclaimer fee for a small entity.

The Examiner's indication that claims 42-44 would be allowable if made subject to a proper terminal disclaimer is gratefully acknowledged. Accordingly, in view of the terminal disclaimer submitted herewith, it is respectfully submitted that claims 42-44 are allowable.

Claims 1, 3-6, 31 and 33-41 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cruzan (U.S. No. 4,036,062), Hansen et al. (U.S. No. 4,022,575), or Parrent et al. (U.S. No. 4,920,060). The Examiner's grounds for rejection are hereinafter traversed, and reconsideration is respectfully requested, particularly in view of the clarifying amendments to the claims.

None of the cited references teach or suggest an apparatus or method for forming a plurality of different selected reagent-mixture ratios by adjusting the flow rate of at least one of the reagent-mixture component streams in accordance with a respective flow rate ratio and then combining the streams to form each selected reagent-mixture, as recited in amended independent claims 1 and 31. To the contrary, the cited references

show no recognition of combining reagent-mixture component streams to create different selected reagent-mixture ratios, much less creating such mixture ratios by adjusting the flow rate of one or more mixture component streams.

In Cruzan, a first conduit having a first volume is filled with diluent, and a second conduit "having a volume bearing a predetermined size relationship" to the first volume is filled with a sample. Cruzan, column 1, lines 57-62. The Examiner has suggested that the oscillator referred to at Cruzan, column 1, lines 62-66, is capable of altering the overall mixture ratio by affecting the ratio of flow through the first conduit relative to the flow through the second conduit.

It is respectfully submitted that the oscillator means merely promotes turbulence to enhance homogeneity of the mixture, and cannot in fact alter the overall ratio of diluent to sample. The fact that the oscillator may impart flow oscillation to at least a portion of the fluid does not require that the oscillator restrict flow in any meaningful way, nor does it define the oscillator as a frequency-valve device. This is confirmed by the fact that the first and second conduits of Cruzan are arranged in a closed-loop series, thus predetermining the mixture ratio according to the original fixed volumes of the first and second conduits. *See* Cruzan, column 1, lines 66-67. Accordingly, the mixture ratio of Cruzan is fixed by the relative volumes of the two conduits, and there is no teaching or suggestion of adjusting the mixture ratio as recited in amended independent claims 1 and 31.

In Parrent, Jr. et al., the sample is introduced through a non-wetting porous membrane 23 into the diluent stream, and the concentration of the resulting mixture is manually controlled by the pressure differential between the sample and diluent sides of the membrane. Although the flow rate on the diluent side may indirectly affect the pressure differential due to the dynamics of fluid flow with a given density and velocity, Parrent et al. show controlling the flow across the membrane via direct control of the sample and diluent fluid pressures via the respective control valves 16' and 16". Parrent

et al. do not show introducing a sample stream directly into a diluent stream, but only show the two streams separated by a selectively porous membrane where the primary sample stream passes by. Therefore, Parrent et al. do not show combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream as recited in amended independent claims 1 and 31.

In Hansen et al., the injector 24 defines a series of bores 32 for receiving hypodermic needles for injecting the samples into the carrier stream traveling through the line 25. The hypodermic needles are shown to be hand operated and are not shown to have accurately controllable flow rates, but merely fixed volumes. *See* Hansen et al., column 4, lines 43-55. Thus, neither of these references teaches or suggests adjusting the flow-rate ratio to form a plurality of different selected reagent mixtures, as recited in amended independent claims 1 and 31.

This claimed feature provides significant advantages over the prior art. One advantage is that the mixture ratio of the reagent mixture may be adjusted at any time, either before or during analysis, by adjusting the flow-rate ratio of the reagent-mixture components. *See* page 18, lines 10 through 23 of the present specification. As also described in the present specification, if, for example, a blood-cell abnormality is detected during hematological analysis, the blood-dilution ratio (which defines the reagent mixture) may be adjusted to further assess the abnormality. With the prior art apparatus, on the other hand, in which the sample batches are prepared in mixing cuvettes, this would require additional samples to be taken or used to further assess the abnormalities. *Id.* Another advantage of creating the reagent mixtures in this manner (as opposed, for example, to using a mixing cuvette), is that a lesser volume of the reagent-mixture components (e.g., blood samples) may be employed. *See* pages 17-18, lines 24 through 9 of the present specification. Yet another advantage of this claimed feature is that in the veterinary market, for example, the system may automatically make the different reagent mixtures for a variety of different animal species by adjusting the flow-

rate ratios in accordance with, for example, a database of information pertaining to the reagent-mixture ratios for the different species. *See* page 14, lines 13 through 21.

Neither these advantages, nor the solution of the present invention for achieving these advantages, as specifically defined in amended independent claims 1 and 31, are taught or suggested by the cited prior art.


It is therefore respectfully submitted that amended independent claims 1 and 31 are not anticipated by Cruzan, Hansen et al. or Parrent, Jr. et al., for at least these reasons. Because claims 3-6 and 33-41 each depend from either independent claim 1 or 31, it is respectfully submitted that these dependent claims likewise are not anticipated by the references of record for at least the same reasons as the independent claims, and for reciting additional patentable subject matter.

Accordingly, it is respectfully submitted that claims 1, 3-6, 31, and 33-44 are allowable. All issues raised by the Examiner having been addressed, an early action to that effect is earnestly solicited.

A Supplemental Information Disclosure Statement citing additional prior art references to supplement those already of record in this application is enclosed herewith. Accordingly, it is respectfully submitted that the Examiner indicate consideration of the cited references by returning a copy of the enclosed form PTO-1449 with initials or other appropriate marks.

Authorization is hereby given to charge the \$345.00 filing fee for the Continued Prosecution Application to our Deposit Account No. 11-0231. No other fee in addition to that submitted herewith is believed to be required. However, if any additional fees are required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our Deposit Account No. 11-0231.

Respectfully submitted,

By 
Eric M. Parham (Reg. No. P-45,747)
Mark D. Giarratana (Reg. No. 32,615)
Attorneys for Applicant

PTO Correspondence Address:

Cummings & Lockwood
Granite Square
700 State Street
P.O. Box 1960
New Haven, CT 06509-1960
Phone: (860) 275-6719
Fax: (860) 560-5919